

**UNITED STATES DISTRICT COURT
DISTRICT OF NORTH DAKOTA
NORTHEASTERN DIVISION**

THE UNIVERSITY OF MANITOBA, a
Manitoban Body Corporate,

Plaintiff,

v.

DRÄGERWERK AG & CO. KGaA, a
German Limited Partnership, and
DRAEGER MEDICAL, INC., a
Pennsylvania Corporation,

Defendant.

Case No: 2:13-cv-00048-RRE-KKK

**DEFENDANTS' RESPONSIVE
CLAIM CONSTRUCTION BRIEF**

I. INTRODUCTION

Only three claims remain in this case from the eight originally apparently asserted by plaintiff. The apparently sole remaining patent in the case, U.S. Patent No. 5,647,350 (“the ‘350 Patent”)¹, contains all three remaining claims. Each of these three claims contains the term at issue in this hearing – “controlled life support conditions” – stated and used in the same way in each claim. The term “controlled life support conditions” was not defined in the specification, it was not described in the specification, it in fact was not included in any fashion in the specification or even in the originally filed claims. The term was added to the application’s claims almost two years after the application’s first priority date in an amendment to the claims in an attempt to distinguish patentee's alleged invention over a prior art patent. In that formal and binding amendment patentee defined a particular limitation to the meaning of that term and

¹ Attached hereto as Exhibit K.

did so twice – in each case in an identical and clear fashion – to distinguish the claims from the prior art patent.

The canons of claim construction are absolutely clear that patentee's characterization of the term "controlled life support conditions" made during prosecution is binding in any later interpretation of the patent claims. Plaintiff's present arguments attempt to import meaning to the term from irrelevancies and are an attempt to substitute a new meaning for the term over the meaning clearly defined in plaintiff's arguments made while trying to obtain allowance of the claims. The law is clear and unavoidable: one cannot argue one meaning of a term in prosecution and propose a different meaning in later litigation.

II. OVERVIEW

Medical ventilators can alternately function according to two different principles. According to the first principle the ventilators work in conjunction with patient breathing efforts to provide respiratory assistance to the patient who is making efforts to breathe. According to the second principle the ventilator operate when the patient is not making any effort to breathe and the ventilator completely controls the breathing of the patient.²

Plaintiff has asserted that the "Variable Pressure Support" ("VPS") option of some Draeger Medical, Inc. ("Draeger") medical ventilators infringes the '350 patent. Draeger is prepared to show that the VPS option of its ventilators ONLY functions when there is patient breathing effort (such as when a patient initiates her/his own breath). Once it detects the patient's effort to initiate a breath, the VPS provides partial assistance to each of the patient's breaths (thus the VPS is termed "Pressure Support" - to support the patient's own breathing). If the Draeger ventilator using the VPS option detects that the patient has ceased breathing efforts

² See, the Declaration of Dr. Edward Sherren, attached as Exhibit A, hereto.

(such as ceasing initiating her/his own breaths) the ventilator immediately alarms out of the VPS mode, ceases VPS operation, and begins an entirely different mode of controlled ventilation of the patient³. Plaintiff has not asserted that the Draeger controlled ventilation (which far predates plaintiff's patent) infringes its patent.

When faced with a rejection (based on a prior art patent termed "Stawitcke") of all its pending claims during the prosecution of the '350 patent, plaintiff formally responded by amending all of the '350 claims – adding the term "controlled life support conditions" to each of them and specifically describing limitations to what plaintiff meant by "controlled life support conditions". Plaintiff twice defined that condition as one in which "there is no patient effort to be taken into consideration." Further, plaintiff explained that under the controlled life condition the ventilator of its alleged invention "wholly controls the flow of ventilating gas to the lungs of the patient under life support." Accordingly, plaintiff specifically disclaimed that its claims apply in a condition where "there is no patient [breathing] effort to be taken into consideration". See First Amendment (February 15, 1996) [Ex. F]. Draeger requests that the court find that the term "controlled life support conditions" mean a "condition where there is no patient breathing effort".

For purposes of the present issues, claim 1 is exemplary of the three claims in the case.

1. A method of controlling flow of a biological fluid to an organ during **controlled life support conditions**, said biological fluid being the primary source of fluid to sustain life support to an organ, wherein said method which comprises:

establishing a predetermined pattern of variations over time of instantaneous changes in flow of a biological fluid to an independently-functioning normal organ of a mammalian species,

³ It should be noted that Draeger is not forfeiting its right to argue non-infringement and/or invalidity for reasons unrelated to "controlled life support conditions."

generating a variable control parameter for regulation of flow of said biological fluid to an organ during **controlled life support conditions** in accordance with said predetermined pattern, and

controlling said flow of said biological fluid to said organ during **controlled life support conditions** in accordance with said variable control parameter to provide a variable flow of said biological fluid to the organ during controlled life support conditions which mimics the normal flow of said biological fluid to a normal organ.

(emphasis added)

III. PATENT CLAIM CONSTRUCTION GENERALLY

While the general rules of claim construction always apply, a particular doctrine of claim construction – prosecution disclaimer – specifically controls in this case. As stated by the Federal Circuit in Omega Engineering, Inc. v. Raytek Corp.:

The doctrine of prosecution disclaimer is well established in Supreme Court precedent, precluding patentees from recapturing through claim interpretation specific meanings disclaimed during prosecution. See Schriber-Schroth Co. v. Cleveland Trust Co., 311 U.S. 211, 220-21 (1940) ('It is a rule of patent construction consistently observed that a claim in a patent as allowed must be read and interpreted with reference to claims that have been cancelled or rejected, and the claims allowed cannot by construction be read to cover what was thus eliminated from the patent.');

Crawford v. Heysinger, 123 U.S. 589, 602-04 (1887); Goodyear Dental Vulcanite Co. v. Davis, 102 U.S. 222, 227 (1880); cf. Graham v. John Deere Co., 383 U.S. 1, 33 (1966) (ruling, in addressing the invalidity of the patents in suit, that 'claims that have been narrowed in order to obtain the issuance of a patent by distinguishing the prior art cannot be sustained to cover that which was previously by limitation eliminated from the patent').

In light of the Court's guidance, we have adopted that doctrine as a fundamental precept in our claim construction jurisprudence. See Tex. Digital Sys., Inc. v. Telegenix, Inc., 308 F.3d 1193, 1204, 64 USPQ2d 1812, 1819 (Fed. Cir. 2002); Hockerson-Halberstadt, Inc. v. Avia Group Int'l, Inc., 222

F.3d 951, 956, 55 USPQ2d 1487, 1491 (Fed. Cir. 2000); Southwall Techs., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1576-77, 34 USPQ2d 1673, 1676-77 (Fed. Cir. 1995); Biodex Corp. v. Loredan Biomedical, Inc., 946 F.2d 850, 863, 20 USPQ2d 1252, 1262 (Fed. Cir. 1991); Standard Oil Co. v. Am. Cyanamid Co., 774 F.2d 448, 452, 227 USPQ 293, 296 (Fed. Cir. 1985) (ruling that 'the prosecution history (or file wrapper) limits the interpretation of claims so as to exclude any interpretation that may have been disclaimed or disavowed during prosecution in order to obtain claim allowance'); McGill Inc. v. John Zink Co., 736 F.2d 666, 673, 221 USPQ 944, 949 (Fed. Cir. 1984). As a basic principle of claim interpretation, prosecution disclaimer promotes the public notice function of the intrinsic evidence and protects the public's reliance on definitive statements made during prosecution. See Digital Biometrics, Inc. v. Identix, Inc., 149 F.3d 1335, 1347, 47 USPQ2d 1418, 1427 (Fed. Cir. 1998).

Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314, 1323-24 (Fed. Cir. 2003).

General Rules of Patent Claim Interpretation

Generally, courts should look to intrinsic evidence, which includes the claims, the specification, and the prosecution history, if possible to help determine the meaning of claims. See, e.g., Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed. Cir. 2005). In many instances, the specification and plain meaning of the claims hold more influence over claim interpretation than the prosecution history. However, the prosecution history can be very helpful in determining the meaning of claim terms. Furthermore, in some instances, such as the circumstances presented in the present case, the claims and specification are no help in defining the meaning of a claim term and the prosecution history is the best source to impart meaning into claim terms.

The general law of claim construction provides that “[i]t is a ‘bedrock principle’ of patent law that ‘the claims of a patent define the invention to which the patentee is entitled the right to exclude.’” Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed. Cir. 2005) (quoting Innova/Pure

Water, Inc. v. Safari Water Filtration Sys., 381 F.3d 1111, 1115 (Fed. Circ. 2004). The words of a claim “are generally given their ordinary and customary meaning.” Phillips, at 1312-1313. Moreover, the “ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill on the art in question at the time of the invention...” Id.

In some instances, the ordinary meaning of claim language as understood by a person of skill in the art may be obvious, and claim construction in such cases involves “little more than the application of the widely accepted meaning of commonly understood words.” Id. at 1314. In such circumstances, a general purpose dictionary may be all that a judge would need. Id.

However, often times the meaning of a claim term as understood by persons of skill in the art is not apparent. In such instances, “the court looks to ‘those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean.’ Those sources include ‘the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art.’” Id. at 1314 (citation omitted). “[T]he person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim ... but in the context of the entire patent”. Id. at 1313.

The specification and prosecution history, both of which are considered intrinsic evidence, should be used for claim construction analysis. See id. at 1317. Both the specification and prosecution history provide “evidence of how the PTO and the inventor understood the patent.” Id. The specification “may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess.” Id. at 1316. Similarly, “the prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the

course of prosecution, making the claim scope narrower than it would otherwise be.” Id. at 1317. As stated by the court in Vitronics Corp. v. Conceptronics, Inc., 90 F.3d 1576 (Fed. Cir. 1996), “the court may also consider the prosecution history of the patent, if in evidence. This history contains the complete record of all the proceedings before the Patent and Trademark Office, including any express representations made by the applicant regarding the scope of the claims. As such, the record before the Patent and Trademark Office is often of critical significance in determining the meaning of the claims.” Id. at 1582 (citations omitted).

In addition to intrinsic evidence, extrinsic evidence, although in general less useful than intrinsic evidence, courts are authorized “to rely on extrinsic evidence, which ‘consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises.’” Id. (quoting Markman v. Westview Instruments, Inc., 52 F.3d 967, 980 (Fed. Cir. 1995). “[E]xtrinsic evidence can help educate the court regarding the field of the invention and can help the court determine what a person of ordinary skill in the art would understand claim terms to mean....” Phillips, at 1319.

In the ‘350 patent the term “controlled life support conditions” is not defined, described, or found in the specification of the patent. Accordingly, inquiry into the specification does not yield a definition for the term. Further, there is no plain language definition of the term. Additionally, Draeger’s expert, Dr. Edward Sherren, confirms that “to the best of my knowledge the term ‘controlled life support conditions’ is not customarily used in describing a patient condition during ventilation and does not have an ordinary meaning to those skilled in the field of ventilation and anesthesiology.”⁴ Thus the court cannot turn to those of ordinary skill in the art for an established definition of the term.

Further, Dr. Sherren has offered his opinion as follows:

⁴ See Exhibit A at paragraph 13.

With respect to ventilation, if one were to propose the term “controlled life support conditions” and characterize it as a condition in which there is no patient effort to be taken into consideration I would conclude that this is a condition in which there is no patient breathing effort.

Again with respect to ventilation, if one were to propose the term “controlled life support conditions” and characterize it as a condition in which a mechanical ventilator wholly controls the flow of ventilating gas to the lungs of the patient under life support I would conclude that this is a condition in which there is no patient breathing effort.⁵

IV. PROSECUTION DISCLAIMER

This case presents a classic instance of prosecution disclaimer. Faced with a rejection of its proposed claims by the patent office, the patentee did not dispute the rejection but chose to amend its patent claims and distinguish the prior art from the amended claims on the basis of the newly added terms to the claims. Moreover, in the same action, the plaintiff specifically defined aspects of the newly introduced terms and described how those aspects distinguished the new claims from the prior art. It is precisely those aspects which distinguish Draeger's devices from plaintiff's claims.

Accordingly, Draeger requests the court to confirm that the added terms to the patent specifically include the aspects and definitions that plaintiff provided to the patent office in obtaining its claims. Claims should not be construed “one way in order to obtain their allowance and in a different way against accused infringers.” Chimie v. PPG Indus., Inc., 402 F.3d 1371, 1384 (Fed.Cir.2005).

⁵ See Exhibit A at paragraphs 14 and 15.

The Law of Prosecution Disclaimer

“The doctrine of prosecution disclaimer ‘protects the public’s reliance on definitive statements made during prosecution’ by ‘precluding patentees from recapturing through claim interpretation specific meanings [clearly and unmistakably] disclaimed during prosecution.” Computer Docking Station Corporation v. Dell, Inc., 519 F.3d 1366, 1374-75 (Fed. Cir. 2005).

The law of prosecution disclaimer is reviewed and well stated in the case of Computer Docking Station, in which, like the instant case, “the specification of the ... patent does not provide an express definition” of the term in dispute. Id. at 1378. In Computer Docking Station the court explained that in some instances the specification of the patent may show that “the patentee has disclaimed subject matter or has otherwise limited the scope of the claims.” Id. at 1374 (citation omitted). The court further explained however that:

Statements made during prosecution may also affect the scope of the claims. [Rexnord Corp. v. Laitram Corp., 274 F.3d 1336, 1343 (Fed. Cir. 2001).] Specifically, “a patentee may limit the meaning of a claim term by making a clear and unmistakable disavowal of scope during prosecution.” Purdue Pharma L.P. v. Endo Pharms., Inc., 438 F.3d 1123, 1136 (Fed. Cir. 2006). A patentee could do so, for example, by clearly characterizing the invention in a way to try to overcome rejections based on prior art. See, e.g., Microsoft Corp. v. Multi-Tech Sys., Inc., 357 F.3d 1340, 1349 (Fed. Cir. 2004) (limiting the term “transmitting” to require direct transmission over telephone line because the patentee stated during prosecution that the invention transmits over a standard telephone line, thus disclaiming transmission over a packet-switched network); Alloc v. Int’l Trade Comm’n, 342 F.3d 1361, 1372 (Fed. Cir. 2003) (finding the patentee expressly disavowed floor paneling systems without “play” because the applicant cited the feature during prosecution to overcome prior art); Bell Atl. Network Servs. v. Covad Commc’ns Group, Inc., 262 F.3d 1258, 1273 (Fed. Cir. 2001) (limiting operation of the “transceiver” to the three stated modes because of clearly limiting statements made by the patentee to try to overcome a prior art rejection). The doctrine of prosecution disclaimer “protects the public’s reliance on definitive statements made during prosecution” by “precluding patentees from recapturing through claim interpretation specific

meanings [clearly and unmistakably] disclaimed during prosecution.” Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314, 1323-24 (Fed. Cir. 2003) (citing in part Schriber-Schroth Co. v. Cleveland Trust Co., 311 U.S. 211, 220-21, 61 S.Ct. 235, 85 L.Ed. 132 (1940)) (bracketed material added). Claims should not be construed “one way in order to obtain their allowance and in a different way against accused infringers.” Chimie v. PPG Indus., 402 F.3d 1371, 1384 (Fed. Cir. 2005)

Computer Docking at 1374-75.

It should be noted, however, that “[p]rosecution disclaimer does not apply to an ambiguous disavowal.” Id. at 1375. However, when the disclaimer is not ambiguous, the authority is clear that “the prosecution history limits the interpretation of claim terms so as to exclude any interpretation that was disclaimed during prosecution.” Southwall Techs., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1576 (Fed. Cir. 1995); see also Ekchian v. Home Depot, Inc., 104 F.3d 1299, 1304 (Fed. Cir. 1997) (“[B]y distinguishing the claimed invention over the prior art, an applicant is indicating what the claims do not cover, he is by implication surrendering such protection.”); Alpex Computer Corp. v. Nintendo of America, Inc., 102 F.3d 1214, 1221 (Fed. Cir. 1996) (“[B]ecause Alpex admitted during prosecution that its claims do not cover a video display system based on shift registers as in Okuda, i.e., it argued that a system based on shift registers is not structurally or functionally equivalent to a RAM based system that can randomly access a single bit, Alpex's claims cannot now be construed to cover the NES, which possesses the same structural and functional traits as Okuda”); Spectrum Int’l, Inc. v. Sterilite Corp., 164 F.3d 1372, 1378 (Fed. Cir. 1998) (“Unambiguous intrinsic evidence in turn provides sufficient input to the rules of claim construction, in particular in this case, the rule that explicit statements made by a patent applicant during prosecution to distinguish a claimed invention over prior art may serve to narrow the scope of a claim.”); Vitronics at 1582 (“[The prosecution] history contains the complete record of all the proceedings before the Patent and Trademark

Office, including any express representations made by the applicant regarding the scope of the claims. As such, the record before the Patent and Trademark Office is often of critical significance in determining the meaning of the claims.”); Phillips Petroleum Co. v. Huntsman Polymers Corp., 157 F.3d 866, 871 (Fed. Cir. 1998) (“We read Edmonds' statements during prosecution as requiring that the polymeric product contain a sufficient amount of block copolymer molecules such that the polymeric product may be properly classified as a ‘block copolymer.’”); Uship Intellectual Props., LLC v. United States, 714 F.3d 1311, 1315 (Fed. Cir. 2013) (“[P]atent applicant's response to a restriction requirement may be used to interpret patent claim terms or as a source of disclaimer.”).

V. THE ‘350 PATENT PROSECUTION HISTORY

The ‘350 patent issued from a patent application (Serial No. 404,464 “the ‘464 application”) filed on March 15, 1995. Plaintiff elected to prosecute three of the original four⁶ claims filed with the ‘464 application – none of which contained the term “controlled life support conditions”. During prosecution the three claims were eventually amended three separate times before they were allowed by the patent office. Since the amendments to each of the three claims were virtually identical in form this memorandum discusses only claim 1 in detail. Exhibit B hereto shows the progression of the amendments to issued claim 1. It was in the first amendment that plaintiff added the term “controlled life support conditions” and specifically distinguished what was covered by the (then) amended claims from the cited prior art ventilator (“Stawitcke”) which apparently did not exhibit “controlled life support conditions”. The second and third amendments were made to distinguish the claims from a different prior art patent (“Blum”) and

⁶ The original ‘464 application included four claims. In response to a PTO Restriction Requirement plaintiff cancelled original claim and continued prosecution on claims 1, 3, and 4 which in amended form eventually issued as claims 1, 2, and 3, respectively, of the ‘350 patent.

dealt not with “controlled life support conditions” but with the constitution of the gases provided to the patient.

In the first official action on the merits (“the First Office Action” attached hereto as Exhibit E) dated November 15, 1995, the PTO rejected all three pending claims for being unpatentable principally over a 1984 prior art patent U.S. Patent No. 4,448,192 (“the Stawitcke patent” attached hereto as Exhibit C). Stawitcke disclosed a ventilator which, among other things, focused on a ventilation system which accommodated patient breathing efforts:

A prime concern of any ventilator is accommodation to patient effort. Accommodation to patient effort, or control by the patient, is defined primarily as synchronization of the ventilator’s inhale and exhale phases with the phases of the patient’s efforts. Secondly it means the ability to deliver air at the rate desired by the patient. In other words, the ventilator with patient effort accommodation allows the patient some control over the ventilator’s operations.

Stawitcke patent at Col. 1, line 65 to Col. 2, line 6.

Stawitcke explained that the type of ventilator it described, by detecting and responding to patient breathing activity provided a method

of providing partial assistance to be used as a mode of therapy or for weaning patients from a ventilator. The assistance is provided at the end of each breath initiated by the patient. The amount of assistance is either set by the clinician or automatically optimized by the ventilator Partially assisting every breath has the advantage of allowing the patient to gradually take over the work of breathing in a more physiological manner than intermittent mandatory ventilation

Stawitcke patent at Col. 5, ll. 29-34 and 56-59.

Stawitcke taught that its system could be used in “weaning patients from a ventilator”⁷ with a varying amount of ventilator assistance provide to the patient “at the end of each breath

⁷ Stawitcke patent at Column 5, lines 30-31.

initiated by the patient.”^{8,9} Plaintiff did not contest the rejection of its claims by the PTO based on Stawitcke but elected on February 15, 1996 (“the First Amendment”)¹⁰ to amend its pending claims and distinguish the amended claims from the Stawitcke teachings.

In the First Amendment, plaintiff amended the claims to add the word “predetermined” and the term “controlled life support conditions” to the claims. Plaintiff’s amendment to claim 1 in the First Amendment is shown in traditional redline form below:

1. A method of controlling flow of a biological fluid to an organ during controlled life support conditions, which comprises:

establishing a predetermined pattern of variations over time of instantaneous changes in flow of a biological fluid to an independently-functioning normal [an] organ of a mammalian species,

generating a variable control parameter for regulation of flow of said biological fluid to an organ during controlled life support conditions in accordance with said predetermined pattern, and

controlling said flow of said biological fluid to said organ during controlled life support conditions in accordance with said variable control parameter.

First Amendment (February 15, 1996) [Ex. F] at 1-2.

What was meant by the term “controlled life support conditions” was not defined or described in the specification of the application. In fact, the term was never used in the ‘464 application prior to this First Amendment. To provide meaning to the term and to distinguish its newly amended claims from the Stawitcke prior art, plaintiff explained an important detail about

⁸ Stawitcke patent at Column 5, line 32.

⁹ Draeger notes that its VPS functions in the same fashion as Stawitcke in that it accommodates patient breathing efforts and provides assistance at the end of the patient breath.

¹⁰ The entire First Amendment is attached hereto as Exhibit F.

what it meant by “controlled life support conditions.” In its comments to the First Amendment plaintiff explained:

The Stawitcke device as relied on by the Examiner is concerned primarily with the weaning type of ventilator which provides assisted ventilation to a patient rather than the present invention which is concerned with ventilation **during controlled life support conditions.**

First Amendment (February 15, 1996) [Ex. F] at 4 (emphasis added).

[The Stawitcke] operation is quite different from the operation in the present invention, where the ventilator is operated **during controlled life support conditions** and not under weaning conditions ... (First Amendment at p. 5)

First Amendment (February 15, 1996) [Ex. F] at 5 (emphasis added).

What is described in Stawitcke in Col. 5 is how the system accommodates patient effort while still maintaining the required target volume ... In the present invention, **there is no patient effort to be taken into consideration** and the variation in respiratory rate and tidal volume is predetermined from a pattern taken from a healthy mammal. (First Amendment at p. 6)

First Amendment (February 15, 1996) [Ex. F] at 6 (emphasis added).

It is clear, therefore, that the Stawitcke reference is concerned with quite different circumstances from the present invention. As already noted, the Stawitcke reference is concerned primarily with the weaning type of ventilator wherein gas flow to the patient is controlled ... to the weaning patient **while taking into account patient effort.** In the absence of patient effort, the system described by Stawitcke will deliver a monotonously regular tidal volume and respiratory rate according to the preset values programmed by the doctor. (First Amendment p. 6)

First Amendment (February 15, 1996) [Ex. F] at 6 (emphasis added).

In contrast, in the present invention, the ventilator is operating during controlled life support conditions where **there is no patient effort to be taken into consideration.** (First Amendment p. 6-7)

First Amendment (February 15, 1996) [Ex. F] at 6-7 (emphasis added).

Although there is no teaching in the ‘350 patent specification as to the totality of the meaning of “controlled life support conditions” it is undeniable that patentee insisted that during “controlled life support conditions” there **is no patient (breathing) effort to be taken into consideration**. Draeger requests the court find that the term “controlled life support conditions” means a “condition where there is no patient breathing effort.” In the alternate Draeger requests the court to determine that patentee has disclaimed that its patent covers a condition except where “there is no patient effort to be taken into consideration.”

In response to plaintiff’s First Amendment the PTO on March 22, 1996 issued a Second Office Action (attached hereto as Exhibit G) in which it rejected the amended claims of the ‘464 application – this time on the basis of prior art U.S. Patent No. 4,584,996 (“the Blum patent” attached hereto as Exhibit D). The Blum patent did not teach a typical ventilator (as did Stawitcke). Instead Blum taught a typical nasal cannula for providing patients with supplementary oxygen. Blum disclosed a variation in flow over time of the oxygen to the patient. Importantly in rejecting the then pending claims over the Blum patent the examiner specified that the Blum patent did not teach “controlled life support conditions”:

Claims 1, 3, and 4 are rejected . . . as being unpatentable over Blum. Blum discloses a method and apparatus for: establishing a predetermined pattern of variation over time of flow of biological fluid (oxygen) to an independently-functioning normal lung [and other features of the claims] Blum does not teach “controlled life support conditions,” the use of the method of Blum in any of a variety of patient care settings would have been obvious to one having ordinary skill in the art depending on a wide variety of patient care criteria.

Second Office Action (March 22, 1996) [Ex. G] at 2 (emphasis added).

In response to the Second Office Action, plaintiff provided another amendment, dated July 2, 1996 (the “Second Amendment” attached hereto as Exhibit H) (which proved to be insufficient) to the claims to distinguish them from the Blum patent. However, it is important to

note that any amendments made to the claims in response to the Blum rejection(s) were not made to modify plaintiff's earlier positions on the meaning of "controlled life support conditions". They were made to address and distinguish other terms or elements of the claims that were taught by Blum. The case law teaches that the purpose of the review of the prosecution history is to identify what the examiner and the applicant understood the alleged invention to be. Phillips, 415 F.3d at 1317. Clearly here the examiner did not consider any response to the Blum reference to relate to "controlled life support conditions".

1. A method of controlling flow of a biological fluid to an organ during controlled life support conditions, which comprises:

establishing a predetermined pattern of variations over time of instantaneous changes in flow of a biological fluid to an independently-functioning normal [an] organ of a mammalian species,

generating a variable control parameter for regulation of flow of said biological fluid to an organ during controlled life support conditions in accordance with said predetermined pattern, and

controlling said flow of said biological fluid to said organ during controlled life support conditions in accordance with said variable control parameter to provide a variable flow of said biological fluid to the organ during controlled life support conditions which mimics the normal flow of said biological fluid to a normal organ.

Second Amendment (July 2, 1996) [Ex. H] at 1-2.

In support of this Second Amendment patentee confirmed again:

The species under consideration herein is a mechanical ventilator which in **a controlled life support scenario, wholly controls the flow of ventilating gas to the lungs of the patient under life support.** In the Office Action, the Examiner concedes that the Blum reference does not teach such controlled life support conditions but nevertheless considers that the use of Blum's

method in any of a variety of patient care settings would have been obvious to one of ordinary skill in the art

It is submitted that the procedure and apparatus of the present invention differ from the Blum procedure and apparatus.

Second Amendment (July 2, 1996) [Ex. H] at 4 and 5 (emphasis added).

This explanation is entirely consistent with and confirms patentee's earlier explanation (in its First Amendment) of "controlled life support conditions". In this explanation there is no patient effort to be taken into consideration since the mechanical ventilator "wholly controls the flow of ventilating gas to the lungs of the patient." It also confirms that Plaintiff's Second Amendment is to address elements or features other than the term "controlled life support conditions" since no challenge to "controlled life support conditions" is presented by the Blum patent.

After this Second Amendment, the Examiner still rejected the pending claims over the Blum patent. In a resulting telephone interview (on July 20, 1996) with the Examiner (a record of which is attached hereto as Exhibit I), an agreement was reached in which an amendment would be entered to distinguish the claims over the Blum patent. This "Third Amendment" (attached hereto as Exhibit J) provided:

1. A method of controlling flow of a biological fluid to an organ during controlled life support conditions, said biological fluid being the primary source of fluid to sustain life support to an organ, wherein said method which comprises:

establishing a predetermined pattern of variations over time of instantaneous changes in flow of a biological fluid to an independently-functioning normal [an] organ of a mammalian species,

generating a variable control parameter for regulation of flow of said biological fluid to an organ during controlled life support conditions in accordance with said predetermined pattern, and

controlling said flow of said biological fluid to said organ during controlled life support conditions in accordance with said variable control parameter to provide a variable flow of said biological fluid to the organ during controlled life support conditions which mimics the normal flow of said biological fluid to a normal organ.

In the Examiner Interview Summary Record (attached hereto as Exhibit I) it records that “Blum teaches oxygen (biological fluid) as a secondary source. Agreement was made to amend claims 1, 3, and 4 – to have the biological fluid as the primary source of fluid to sustain life. This Amendment to Claims 1, 3, and 4 will put this claim (sic) in condition for allowance.” This the purpose of the Third Amendment was to distinguish the claims over Blum’s providing supplemental oxygen to a patient via a cannula. This amendment had nothing to do with “controlled life support conditions.”

The Third Amendment was formalized and entered into the prosecution history in an Notice of Allowability dated February 3, 1997 (attached hereto as Exhibit J).

VI. “CONTROLLED LIFE SUPPORT CONDITIONS” AND “PRIMARY SOURCE” OF FLUIDS

Draeger does not contest that the term “said biological fluid being the primary source of fluid to sustain life support to an organ” is in the claim. Draeger contends though that the term simply has nothing to do with interpretation of the term “controlled life support conditions” as used in the claims.

First, the “primary source” term pertains to the biological fluids. The “controlled life support conditions” has to do with the condition of the patient. There is no logical or technical connection between the two terms that should affect the proper interpretation of “controlled life support conditions”.

Second, the Third Amendment which added the “primary source” term to the claims was in response to the rejection over the Blum reference which both the examiner and plaintiff agreed did not relate to or teach “controlled life support conditions”. Accordingly, the Third Amendment had no impact on changing the limitations plaintiff had already put in place on “controlled life support conditions”. Further, it is presumed that the Stawitcke patent disclosed a typical ventilator where the ventilator provided the “primary source” of fluids for the patient. Reading any reductions in the limitations of “controlled life support conditions” as plaintiff proposes would then render the claims indistinguishable and unpatentable over Stawitcke again.

Additionally, plaintiff proposes a “straw man” issue between the terms “primary” and “sole”. The word “sole” is not found anywhere in the ‘350 patent. Draeger has asked the court to define the term “controlled life support conditions” and not “primary” or “primary source” and certainly not “sole”.

Plaintiff’s attempts to somehow lever implications from the term “primary source” into its clearly defined “controlled life support conditions” is not enabled by the canons of claim construction. It is in fact however directly contrary to one of the most fundamental of those canons – that claims should not be construed “one way in order to obtain their allowance and in a different way against accused infringers.” Chimie, 402 F.3d at 1384.

VII. CONCLUSION

For the reasons set forth above, Draeger asserts that the proper interpretation of the term “controlled life support conditions” is a “condition where there is no patient breathing effort” and requests the Court to so find.

DATED this 4th day of March, 2014.

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**UNITED STATES DISTRICT COURT
DISTRICT OF NORTH DAKOTA
NORTHEASTERN DIVISION**

THE UNIVERSITY OF MANITOBA, a)	
Manitoban Body Corporate,)	Case No: 2:13-cv-00048-RRE-KKK
)	
Plaintiff,)	
)	
v.)	
)	
DRÄGERWERK AG & CO. KGaA, a)	CERTIFICATE OF SERVICE
German Limited Partnership, and)	
DRAEGER MEDICAL, INC., a)	
Pennsylvania Corporation,)	
)	
Defendant.)	

I hereby certify that on March 4, 2014, the following document(s):

1. Defendants' Responsive Claim Construction Brief

was filed electronically with the Clerk of Court through ECF, and that ECF will send a Notice of Electronic Filing (NEF) to the following:

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I further certify that a copy of the foregoing documents will be mailed by first class mail, postage paid, to the following non-ECF participants:

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